K051961

FEB 1 0 2006

Section 4
Summary of Safety & Effectiveness

10 May 2005

The ***wwMed*** ™ ***Model 401*** is designed to be used only according to the Indications for Use, which are: "This device *is intended to emit energy in the infrared spectrum to provide topical heating for use when heat is indicated in the temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis, and promoting relaxation of the muscle.*

This system is for clinical applications to provide low level light therapy. As such, *this device* is a Class II device, having Regulation Number: ***21 CFR part 890.5500. Product Code ILY.***

This summary is submitted in behalf of:

Wong Way Corporation
3 Alpine Lane,
Darien, CT, USA 06820
Voice phone number-203 363 0676
Fax phone number- 203 363 0676

This summary is submitted by:

Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, Connecticut, 06907
voice phone number (203) 329 2700)
fax phone number (203) 329 2345.

This device can be **described** as a Class II Low Level Light treatment process employing the application of energy, which penetrates the skin surface to the underlying tissues, and triggers normal cellular functions that lead to a surgery-free, drug-free, and low cost benefit to the patient, the practitioner and the health care system. This device uses proprietary techniques and computational processes.

The **scientific concept** on which this device is based is the principle that by stimulating a local area with low level light to relieve pain.

The **intended use** of this device is for a trained health care professional to diagnose that specific patients would benefit from this therapy and treat patients for specific ailments using specific protocols.

This is a *prescription only* device. The labeling, instructions and user operations are designed for health care professionals.

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Wong Way Corporation has determined that this device is substantially equivalent to the Palomar Lightcube, manufactured by Palomar Medical Products, which are currently in commerce as: K024179.

A factory calibration test is conducted to verify the device is accurate and calibrated (and can maintain calibration over its useful life). The ***wwMed ™ Model 401*** has benefited from design, development, testing and production procedures that conform to Quality Systems.

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. ***Wong Way Corporation*** continues to search all appropriate sources for information relating to safety and effectiveness and maintains an *in-house* reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

CERTIFICATION:
I hereby certify this **Summary of Safety and Effectiveness** applies for the above indicated device.

Dr. Edmund Wong
Chairman
Wong Way Corporation
3 Alpine Lane,
Darien, CT, USA 06820
Voice 203 363 0676
Fax 203 363 0676

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2006

Wong Way Corporation
c/o Mr. Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, Connecticut 06907

Re: K051961
Trade/Device Name: wwMed™ Model 401
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: January 30, 2006
Received: February 2, 2006

Dear Mr. Keen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2
Indications for Use

510(K) Number (If known): __051961_____

Device Name: *wwMed ™ Model 401*

Indication For Use:

The ***wwMed ™ Model 401*** *is intended to emit energy in the infrared spectrum to provide topical heating for use when heat is indicated in the temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis, and promoting relaxation of muscles.*

Prescription Use __XXX___ **AND/OR** **Over - The - Counter Use** _____
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off) _____ _____
Division of General, Restorative, and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

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